AMENDMENTS TO THE CLAIMS

1. Pursuant to 37 C.F.R. § 1.121(c),this separate paper is submitted showing the claim listing of all claims ever presented in the instant case.

1. (Original) A microparticle for use in the pulmonary delivery of a therapeutic material, comprising a polymer matrix, wherein said polymer matrix is prefabricated in a particular geometric shape.

2. (Original) The microparticle of claim 1, wherein said microparticle has a geometric diameter or width of about 1 to 100 microns and a thickness of about 1 to 10 microns.

3. (Original) The microparticle of claim 1, wherein said geometric shape is that of a disc, cube, rectangle, or snowflake.

4. (Original) The microparticle of claim 1, wherein said therapeutic material is a drug.

5. (Original) The microparticle of claim 1, wherein said therapeutic material is a biologically active material selected from the group consisting of enzymes, hormones, proteins, antibodies, vitamins, peptides, polypeptides, nucleic acids, oligonucleotides, vaccines, cells, antigens, allergens, viruses, and combinations thereof.

6. (Original) The microparticle of claim 1, wherein said therapeutic material is bound to, incorporated in, or encapsulated by said polymer matrix.

7. (Original) The microparticle of claim 1, wherein said polymer matrix comprises at least one biodegradable or biocompatible polymer.

8. (Original) The microparticle of claim 7, wherein said at least one biodegradable or biocompatible polymer is polylactide or polyphosphazene.

9. (Original) The microparticle of claim 1, wherein said polymer matrix further comprises at least one additional polymer for enhancing the degradation characteristics of said polymer matrix, wherein said at least one additional polymer is selected from the group consisting of polyacrylic acid, polystyrene sulfonic acid, polyphosphazene, poly-L-lysine, polyaspartic acid, polymethacrylic acid, imidazole, polyglutamic acid, glycine, polystyrene maleic anhydride copolymers, polyvinylamine, polyamino acids, polyvinylpyrindine, vinylether maleic anhydride copolymers, styrene-acrylic acid copolymers, and combination thereof.

10. (Original) The microparticle of claim 1, wherein said microparticle is aerosolizable by dry powder nebulizers, liquid nebulizers, and electrostatic sprayers.

11. (Currently Amended) A method for making [[a]] the shaped microparticle of claim 1 ~~for use in the pulmonary delivery of a therapeutic material,~~ comprising the steps of:

(a) selecting at least one polymer ~~or other material~~ to form said shaped microparticle; and

(b) employing a microfabrication technique to form said shaped microparticles, wherein said technique consists of cutting said microparticles from sheets of polymer by photolithography, microstamping said microparticles from sheets of polymer, or casting said microparticles in molds.

12. (Currently Amended) A method for making [[a]] the microparticle of claim 1, further ~~for use in the pulmonary delivery of a drug,~~ comprising the step of sandwiching a drug-containing polymer layer between two other polymer layers.

13. (Currently Amended) [[A]] The method of claim 12, further ~~for making a microparticle for use in the pulmonary delivery of a drug,~~ comprising the steps of:

(a) drying a biodegradable polymer which has been dissolved in an organic solvent in a micro-mold, or casting said biodegradable polymer as a sheet;

(b) adding [[a]] the drug-containing polymer layer ~~second layer of biodegradable polymer which contains said drug~~ to said micromolded or cast biodegradable polymer layer; and

(c) adding a third biodegradable polymer layer to the top of said drug-containing polymer layer, wherein a laminar system is formed.

14. (Original) The method of claim 13, wherein said biodegradable polymer is poly(lactic-co-glycolic acid, and said organic solvent is methylene chloride.

15. (Currently Amended) A method for making a microparticle for use in the pulmonary delivery of a protein, comprising the steps of:

(a) lyophilizing a protein solution in a micro-mold;

(b) compressing said lyophilized protein with a micro-tool compatible with said micro-mold; and

(c) sandwiching said lyophilized protein between a first polymer layer and a second polymer layer, the second polymer layer comprising the microparticle of claim 1.

16. (Original) The method of claim 15, wherein the polymers of said first polymer layer and said second polymer layers are biodegradable polymers.

17. (Original) The method of claim 15, wherein said first polymer layer is dried in said micro-mold prior to addition said protein, and said second polymer layer is added after said protein is compressed.

18. (Currently Amended) A shaped, particulate dry powder composition comprising the microparticle of claim 1 suitable for aerosolization and delivery to the pulmonary system of a patient in need of treatment, the composition further comprising a therapeutically effective amount of a biologically active agent and at least one physiologically acceptable polymer wherein said biologically active agent is contained in said polymer.

19. (Original) A composition according to claim 18 wherein the shape of said shaped particles is selected from a disc, a cube, a rectangle and a snowflake.

20. (Original) A composition according to claim 19 wherein the diameter of said shaped particles is from about 1.0 to from about 100.0μ and wherein the shaped particle is from about 0.5μ to about 1.5μ thick.

21. (Original) A composition according to claim 18 wherein the biologically active agent is a protein, polypeptide or peptide.

22. (Original) A composition according to claim 21 wherein said biologically active protein, peptide or polypeptide is an enzyme, hormone, growth factor, antibody, or cytokine.

23. (Original) A composition according to claim 22 wherein said biologically active agent is selected from the group consisting of ascorbate oxidase, peroxidase, catalase, glucose oxidase, chymotripsin, lactate dehydrogenase, glucose-6-phosphate dehydrogenase, trastuzumab, muromonab- CD3, insulin, human growth hormone (HGH), fibroblast growth factor (FGF), nerve growth factor (NGF), human growth hormone releasing factor (HGHRF), leukemia inhibitory factor (LIF), granulocyte-colony stimulating factor (G-CSF), granulocyte macrophage-colony stimulating factor (GM-CSF), interleukin-6 (IL-6), interleukin-11 (IL-11), interleukin-9 (IL-9), oncostatin-M (OSM), and Factor VIII.

24. (Currently Amended) A composition according to claim 18 wherein said polymer is selected from the group consisting of PLGA, polyphosphazene, poly[(p-carboxyphenoxy)-hexane anhydride] (PCPH), polyglycolic acid (PGA), polylactic acid (PLA), polyethylene, polypropylene, poly (ethylene glycol), and poly(ethylene oxide).

25. (Original) A composition according to claim 24 wherein said polymer is PLGA.

26. (Original) A composition according to claim 18 containing from 0.1% to from about 5.0% of a pharmaceutically acceptable excipient.

27. (Original) A composition according to claim 26 wherein said excipient is selected from the group consisting essentially of surfactants, antioxidants, antimicrobials, suspending agents, and sugars.

28. (Original) A composition according to claim 18 wherein the shaped particle contains a second polymer that functions to slow the release of the active therapeutic agent from the particle.

29. (Original) A composition according to claim 28 wherein said second polymer that functions to slow the release of the active therapeutic agent from the particle.